

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

MEDTRONIC, INC., AND MEDTRONIC VASCULAR, INC.,

Petitioners,

v.

TELEFLEX INNOVATIONS S.À.R.L.,

Patent Owner.

IPR2020-00126 (U.S. Patent No. 8,048,032)

IPR2020-00127 (U.S. Patent No. 8,048,032)

IPR2020-00128 (U.S. Patent No. RE45,380)

IPR2020-00129 (U.S. Patent No. RE45,380)

IPR2020-00130 (U.S. Patent No. RE45,380)

IPR2020-00132 (U.S. Patent No. RE45,760)

IPR2020-00134 (U.S. Patent No. RE45,760)

IPR2020-00135 (U.S. Patent No. RE45,776)

IPR2020-00136 (U.S. Patent No. RE45,776)

IPR2020-00137 (U.S. Patent No. RE47,379)

IPR2020-00138 (U.S. Patent No. RE47,379)

**DECLARATION OF PAUL ZALESKY SUBMITTED IN SUPPORT OF
PETITIONERS' OPPOSITIONS TO PATENT OWNER'S
MOTIONS TO AMEND**

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I. Introduction

1. I have been retained by Robins Kaplan LLP on behalf of Medtronic, Inc., and Medtronic Vascular, Inc., (“Medtronic”) as an independent expert to provide my opinions in connection with *Inter Partes* Review (“IPR”) petitions that have been instituted on five patents: U.S. Pat. Nos. 8,048,032; RE45,380; RE45,760; RE45,776; and RE47,379 (the “Root patents”): IPR2020-00126, -00127, -00128, -00129, -00130, -00132, -00134, -00135, -00136, -00137, and -00138 (“IPRs”).

2. I make this declaration based on personal knowledge. I am over the age of 21 and am otherwise competent to make this declaration.

II. Qualifications

3. I summarize my educational background and career history in the following paragraphs. My curriculum vitae is attached as Exhibit 1 to this declaration.

4. Following achievement of a B.S. (Univ. of Notre Dame) and M.S. (Univ. of Michigan) in Aerospace Engineering, I attained a PhD in Biomedical Engineering (Univ. of Michigan), publishing my thesis research on the prediction of optimal surgical timing for the repair of Congenital Heart Defects. My industrial career has been focused on the development and commercialization of specialty medical devices for the diagnosis and treatment of heart disease, encompassing

more than 30 years of management and engineering positions in both large and small companies.

5. Following the initiation of “interventional” cardiology by Dr. Andreas Gruntzig in the late ’70s, when he pioneered coronary balloon angioplasty, the 1980s saw the evolution of least invasive treatments of coronary artery disease (CAD). Today, those treatments are generally referred to as interventional cardiology. I became directly involved in the development of devices associated with interventional cardiology. In 1986, I led Boston Scientific’s entry into the coronary angioplasty (PTCA) market as Director of R&D, presenting device efficacy data to the FDA towards a soon-approved Pre-Market Application (PMA). In that role I also supervised the development of guide catheters and guidewires needed as accessories to angioplasty.

6. Later in 1986, I co-founded InterTherapy with cardiologist Dr. Walt Henry. InterTherapy was focused on the development of intravascular ultrasound for assessment of coronary disease that directed subsequent therapy. The disposable component of the product was a 5 French coronary catheter with design and materials that enabled its passage through standard guide catheters into the branches of the coronary artery. From 1986 through 1990 I managed all company operations, with an emphasis on device use in the cardiac catheterization labs of Center of Excellence hospitals.

7. I recruited, and worked closely with, Dr. Martin Leon, then a Fellow at the National Institutes of Health, and collaborated with Dr. Leon on the creation of a new, interventional cardiology symposium, Transcatheter Cardiovascular Therapeutics, which subsequently evolved into the largest and most comprehensive symposium in the field of interventional cardiology. I also collaborated closely with cardiologists from multiple U.S. and European Centers of Excellence, including the Mayo Clinic, Mass General Hospital, UCLA, Rhode Island Hospital, Emory University, Stanford University, Clinico Cardiologica in Milan, Italy, and many others. In this, and subsequent professional positions, I participated in hundreds of patient cases in the cardiac catheterization lab, donning protective lead aprons while assisting or observing patient cases. The InterTherapy technology effectively enabled the development and evolution of coronary stents, as the real-time, intravascular imaging enabled review and optimization of stent deployment.

8. In the early '90s I served as Vice President of R&D for a division of Baxter International, where I led the development of and presented the corporation's interventional cardiology product portfolio to cardiologists and associated symposia, including the development of critical devices for treatment of CAD.

9. In 1995 I co-founded, with cardiologist Dr. J. Richard Spears, TherOx. TherOx was focused on the development of oxygen supersaturated

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